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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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ART UNIT PAPER NUMBER

DATE MAILED:

04/17/96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	08/487,701	Applicant(s)	Gray et al.
Examiner	Ardin Manschel	Group Art Unit	1809

Responsive to communication(s) filed on 9/3/97

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 48-94 is/are pending in the application.
~~the above~~ Claim(s) 1-47 ~~have been canceled.~~
~~the above~~ are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 48-94 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

It is hereby acknowledged that applicants have filed a petition under 37 CFR § 1.129(a). As a result the finality of the office action, mailed 9/3/96, is hereby withdrawn. The amendment, filed 9/3/97, has been entered.

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1809.

Applicants' arguments, filed 9/3/97, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

If applicants desire priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application.

Drawings in colors other than black and white do not come within the purview of 37 CFR 1.84. Unless the drawing requirements of 37 CFR 1.84 are waived, the draftsman will not approve color drawings in a utility or design patent application. Thus, Figures 13A-13I, 14, 15A, 15B, 16A, 16B, 17A, 17B, 18A, 18B, 19A, 19B, 20, and 21 are improper and applicants must either

cancel the drawings or provide substitute black and white drawings.

Neither the examiner nor the draftsman have the authority to waive or suspend drawing requirements to permit color drawings in utility and design applications. Applicants may file a petition under 37 CFR 1.183 with fee requesting acceptance of the color drawings and a waiver of the requirements of 37 CFR 1.84. The petition and application file must be sent to the Deputy Assistant Commissioner for Patents for decision. Only if the petition is granted will the draftsman be authorized to approve the color drawings as to form.

Where color drawings have been transferred from a prior application to a newly submitted application, applicants must renew the petition under 37 CFR 1.183 even though a similar petition was filed in the prior application. Until the renewed petition is granted, the examiner must object to the color drawings as improper. See MPEP 608.02.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 94 is rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to retinoblastoma rearrangement detection wherein there is used the

specific primers showing chromosomal rearrangements involving chromosomes 13 and 21 as given in Example IX starting on page 130 of the specification. There is no guidance or enablement of involvement of other chromosomes or primers. Additionally, the reference cited by applicants as Bowcock et al. has been enclosed in the previous office action and summarizes in the abstract that the linkage between the chromosome 13 RB gene and cancer is not clear and may be secondary or present in some tumors only by chance. Thus even the instantly discussed rearrangement is in question as to its enablement. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 72-94 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Weissman et al.

The instant invention is directed to the use of high complexity probes, from which repetitive sequences have been removed, for hybridization labeling of chromosomes to detect unique segment nucleic acids in chromosomal DNA that is present in a morphologically identifiable chromosome or cell nucleus during in-situ hybridization.

Weissman et al. disclose in columns 5-6, bridging paragraph, that the invention therein described detects chromosomal arrangements such as the spacing between genes including linkage that may be related to a disease. Probed regions are disclosed as 50 kb to 2000 kb in column 9, lines 14-32, which clearly qualifies as high complexity probes as instantly claimed. The coverage of the probed region is accomplished as depicted in Figure 5 (discussed in column 18, lines 32-62) and discussed as to probes prepared in the bridging paragraph between columns 18 and 19. Weissman et al. lacks the specific retinoblastoma rearrangement disclosure but is motivated to study such rearrangements as summarized in column 2, line 13, through column 4, line 5.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice high complexity probes and their use in hybridization assay as instantly claimed because Weissman et al. disclose the method and the motivation to apply this to diseases suspected of being caused by genetic rearrangements such as retinoblastoma gene rearrangements that result in cancer etc. Applicants argue that this reference does not include in-situ hybridization wherein morphologically identifiable chromosomes are analyzed. In response, applicants are pointed in the reference to column 18, line 30, to column 19, line 38, wherein in-situ hybridization is disclosed including fluorescence microscopy as well as the spreading of chromosomes for analysis. Morphologically identifiable chromosomes are well known to be observed in such chromosome spreads. Polytene chromosomes are described which also are well known as morphologically identifiable chromosomes. Other chromosome localizations are discussed in the reference which clearly directs analysis to morphologically identifiable chromosomes. Applicants also argue that the reference does not cite the removal of repetitive sequences from complex nucleic acids to result in unique copy probes. In response, Weissman et al. describes the isolation of DNA segments of greater than 40 KB in size in column 28, lines 16-23. Analysis then proceeds for single copy segments and in column 28, lines 54-63, multiple copy segments were either discarded or subjected to subcloning. The probe preparation continues with the single or unique copy

segments.

Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as the U.S. Patent 5,447,841 reference at the time this invention was made. Accordingly, the U.S. Patent 5,447,841 reference is disqualified as prior art through 35 U.S.C. § 102(f) or (g) in any rejection under 35 U.S.C. § 103(a) in this application. However, this reference additionally qualifies as prior art under section (e) of 35 U.S.C. § 102 and accordingly is not disqualified as prior art under 35 U.S.C. § 103(a).

Applicant may overcome the reference either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another", or by antedating the reference under 37 CFR 1.131.

Claims 48-94 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,447,841. This rejection is based on the disclosure of the invention in said patent and the different inventive entity between the patent and the instant application.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*,

759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,447,841. Although the conflicting claims are not identical, they are not patentably distinct from each other because common embodiments exist between the two sets of claims in that the probe complexity of the instant claims is greater than about 40 kb whereas any complexity of probe is within the scope of the cited patent, everything else being the same in the claims.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-7401 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

September 26, 1997

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER
GROUP 1800